

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEPRACOR INC.,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 06-113 (LPS)
)	(Consolidated)
DEY, L.P., DEY, INC., MYLAN INC. and)	
MYLAN PHARMACEUTICALS INC.,)	
)	
Defendants.)	

JOINT STATUS REPORT

Pursuant to the Court's November 2, 2010 Order, the Parties respectfully submit this Joint Status Report.

I. NATURE OF THE ACTION

Plaintiff Sepracor Inc. (now known as Sunovion Pharmaceuticals Inc., "Sunovion") and Defendants Dey, L.P. (now known as Dey Pharma L.P.), Dey, Inc., Mylan, Inc., and Mylan Pharmaceuticals, Inc. (collectively "Dey") jointly submit this letter in response to the Court's November 2, 2010 Order requesting a status report in these cases.

Sunovion filed civil action nos. 06-113 and 06-604 on February 22, 2006 and September 27, 2006, respectively, pursuant to the Hatch-Waxman Act, 35 U.S.C. § 271(e) alleging infringement of U.S. Patent Nos. 5,362,755, 5,547,994, 5,760,090, 5,844,002 and 6,083,993 (collectively "method-of-use patents")¹. Sunovion seeks to enjoin Dey from commercially

¹ Dey is one of three companies that Sunovion sued within forty-five days, after being notified that ANDA applications with Paragraph IV certifications were filed seeking approval to market generic versions of Xopenex ® before the expiration of Sunovion's relevant patents. Sunovion filed the first suit against Defendant Breath Limited in the District of Massachusetts, C.A. No. 06-10043-DPW, on October 21, 2005 (the "Breath case"). On February 22, 2006 and September 27, 2006, Sunovion filed suit against Defendants Dey, L.P. and Dey, Inc., in this district, C.A. Nos. 06-113 and 06-604 (LPS), which have been consolidated under C.A. No. 06-113 (LPS). On July 12, 2007,

making, using, selling or offering for sale the generic levalbuterol hydrochloride inhalation solutions that are the subject of Dey's ANDA Nos. 77-800 and 78-309.² (*See* D.I. 412.) Dey counterclaimed that its ANDA products do not infringe the method of use patents and/or are invalid and/or unenforceable due to inequitable conduct before the U.S. Patent and Trademark Office. (*See*, e.g., D.I. 415.) These cases were consolidated under C.A. No. 06-113.

II. STATUS OF DISCOVERY

Under the applicable scheduling orders, the Court's deadline for fact discovery on the liability issues was December 2007. Judge Farnan issued a Markman decision on December 18, 2008. (D.I. 312.) The Court's deadline for expert discovery on the liability issues was April 2009. Judge Farnan ruled on the parties' dispositive motions on September 24, 2009. (D.I. 392.)

Dey launched its concentrate strength of levalbuterol hydrochloride solutions at risk on August 28, 2009. On October 7, 2009, Sunovion amended its complaint to add a claim for damages. Under the current schedule, fact and expert discovery on the damages issues are scheduled to be completed by November 19, 2010 and March 18, 2011, respectively. (D.I. 420.) Dates for the pretrial conference and trial have not been set.

The parties have scheduled mediation conference with Magistrate Judge Thyng, which will take place tomorrow, Wednesday, November 10, 2010.

Sunovion filed suit against Defendant Barr Laboratories, Inc. in this district, C.A. No. 07-438 JJF (the "Barr case"). The Breath and Barr cases subsequently settled.

² Sunovion sued Dey on only five of the Orange Book patents ("method-of-use patents"). The sixth patent is the subject of a separate declaratory judgment action brought by Dey against Sunovion, civil action no. 08-372-LPS.

III. SCHEDULING

Each party has raised its own discovery-related issues. The parties have met and conferred and are working through the remaining issues. As a result of these outstanding discovery issues, Dey believes that the current schedule should be amended to provide additional time for fact discovery. The parties are discussing those issues and will approach the Court if they are unable to agree.

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